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Compressive stockings after hindfoot and ankle surgery

Grubhofer, Florian ; Catanzaro, Sabrina ; Schüpbach, Regula ; Imam, Mohamed A ; Wirth, Stephan

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Compressive Stockings After Hindfoot and Ankle Surgery

Florian Grubhofer, MD[1], Sabrina Catanzaro, RN[1], Regula Schüpbach, RN[1], Mohamed A. Imam, PhD, FRCS[1,2,3], and Stephan Wirth, MD[1]

Abstract

Background: Swelling and pain are common after foot and ankle procedures. We hypothesized that compressive stockings (CS) treatment after hindfoot surgery would positively influence patient outcomes.

Methods: We undertook this randomized controlled trial in 87 consecutive patients to analyze the clinical effect of CS after hindfoot and ankle surgery and evaluate CS-wearing compliance using sensors that were implanted into CS. Ankle swelling, pain status, quality of life (SF-36 score), and the American Orthopaedic Foot & Ankle Score (AOFAS) were set as the primary end points. The CS wearing time in hours and percentage were investigated as the secondary end points. All participants with CS (group I) were informed about the implanted sensor after the CS were taken off. A subgroup analysis of group I was performed to detect differences between patients with high vs low compliance.

Results: At 12 weeks, the results of ankle swelling (mean 234 mm in group I and 232 mm in group II), pain in the visual analog scale (1.7 group I vs 1.9 in group II), the SF-36 score (38 points in group I vs 30 points in group II), and the AOFAS score (a mean of 76 points in both groups) showed no statistical differences between the 2 groups. The mean wearing time was 136 (range, 0-470) hours, which corresponds to a compliance rate of 65%. Sixteen participants had high compliance (>80%, >170 hours), and 21 patients had low or noncompliance. The clinical results of patients with high wearing compliance were not significantly better compared to the results of patients with low compliance.

Conclusion: CS therapy after ankle and hindfoot surgery was associated with a low wearing compliance and did not influence ankle swelling, function, pain, and the quality of life compared to the control group. Furthermore, the clinical results of patients with high compliance were not better compared to the results of patients with low or noncompliance wearing behavior.

Level of Evidence: Level II, prospective randomized study of lower quality.

Keywords: compressive stockings, sensor-controlled compliance analysis, foot and ankle surgery

Swelling is associated with stiffness and unsatisfactory outcomes after ankle surgery.[2,5,8,12] Therefore, reduction of ankle swelling after foot and ankle surgery is desired. Compressive stockings (CS) therapy is purported to prevent deep vein thrombosis and postthrombotic syndrome in case of prolonged immobilization.[4,10,11] In addition, the use of CS appears to reduce ankle swelling and correlates with superior ankle function, reduced pain, and improved quality-of-life scores after ankle fractures and open ankle surgery.[2,13,15] But for CS to be efficient, patients should wear them as advised. We cannot speculate or study the efficacy of a postoperative CS therapy without assessing patients' wearing compliance. It is known that patients' compliance analysis by a questionnaire is not reliable.[1,7,9,14,16]

The primary aim of this randomized controlled study was to evaluate functional outcomes and quality of life of patients undergoing ankle and hindfoot surgery with vs without the use of postoperative CS. The secondary objective of this clinical study was to evaluate the CS wearing time and patients' compliance by the use of a sensor device, which was implanted covertly into the CS. We tested the hypothesis of whether wearing CS would translate to improved ankle swelling status, reduced pain, better American Orthopaedic Foot & Ankle Score (AOFAS) score, and better quality of life.

[1]Department of Orthopaedics, University of Zurich, Balgrist University Hospital, Zürich, Switzerland
[2]Oxford University Hospitals, Oxford, UK
[3]Senior Lecturer Suez Canal University, Ismailia, Egypt

Corresponding Author:
Florian Grubhofer, MD, Orthopaedic Department, Balgrist University Hospital, University of Zurich, Forchstrasse 340, Zurich, CH-8008, Switzerland.
Email: florian.grubhofer@balgrist.ch

Methods

The study was a single-center, single-blind, prospective randomized study involving patients undergoing hindfoot surgery. The study protocol, participant information sheet and consent forms, and patient-reported questionnaires were submitted and approved by the local ethical committee of Zurich, Switzerland, prior to study initiation. The study protocol was registered at clinicaltrials.gov as NCT02792907.

The participant population was adult male and female patients who were listed for a foot and ankle surgery at the University Hospital Balgrist. Our inclusion criteria included patients willing to undergo standardized postoperative physiotherapy, comply with postoperative instructions, willing to be randomized to 1 of 2 groups, and able to provide consent by themselves. The patients were informed about the intention of the study in advance but were not primarily informed about the use of the temperature-capturing sensor, which was implanted in the CS so as to assess their compliance. A second consent form was obtained after the participants were informed about the implanted sensor. This information was given retrospectively after the CS treatment was terminated. If the participants denied further study participation, the patient was excluded from the study and the information from the sensors was deleted. The exclusion criteria for the study were patients with a contraindication for the use of CS, patients who were treated with an external fixator, and patients who could not provide written informed consent for participation in the study. Patients with postoperative cast treatment were not excluded from the study because compressive stockings were wearable beneath the split casts. Patients whose prospects for a recovery to independent mobility would be compromised by known coexistent, medical problems like cancer or advanced rheumatoid arthritis were also excluded from the study. All participants were encouraged to remain in the study through to 12 weeks postsurgery; nevertheless, participants had the right to voluntarily withdraw from the study at any time for any reason. All potential participants were screened for eligibility by their surgeon or trained member of the research department.

The participants were randomized and blindly assigned with sealed envelopes into group I, in which all participants had to wear CS for 4 weeks, or into group II, which served as the control group in which CS therapy was not used. Primarily, the patients were subdivided into forefoot, midfoot, and hindfoot subdivisions. After 4 patients of the forefoot and midfoot group claimed discomfort during dressing and undressing the CS over the operated foot, the study protocol was changed and only patients with hindfoot and ankle surgeries were included because these patients had no problems with wearing and undressing the CS. All data from the study participants were collected and encoded online in the REDCap software system (Vanderbilt University Medical Center, Nashville, TN).

From July 2016 to January 2017, a total of 90 patients were recruited as participants. Final analysis was performed in 76 (41 female and 35 male) patients with a mean age of 46 (range, 18-79) years. The mean body weight was 80 (range, 47-130) kg. The 76 patients were randomly assigned into the 2 groups, with 37 patients in the CS group and 39 patients in the control group. The indications of ankle and hindfoot surgery are listed in Table 1. There were no statistical differences between the groups according to age, sex, and weight (Figure 1).

Three patients did not meet the inclusion criteria after randomization. One participant had a wound-healing problem and another patient showed severe swelling of the operated foot so that adjustment of the CS was impossible, and both were excluded. Two participants disposed the compressive stockings into the garbage and were therefore excluded from the study. Two participants of the intervention group and 4 participants of the control group withdrew. One participant of the intervention group denied the readout of the sensor and subsequently withdrew (Figure 2).

Intervention

The patients who were randomized into group I (the "stockings group") received a knee-high class II CS with 23- to 32-mm Hg pressure (Mediven, Bayreuth, Germany) on the operated foot after the stiches were removed 14 days after the index surgery. The size of the CS was determined after an experienced orthopedic technician measured the intermalleolar diameter. The patients were instructed to wear the CS for at least 8 hours daily until the 6-week appointment postsurgery. A sensor (Orthotimer, Balingen, Germany) was implanted into the top of the stocking (Figure 3). The certificated sensor measured the surrounding temperature with an accuracy of 0.01°C every 15 minutes. The sensor has a capture threshold of 33°C, which means that if the surrounding temperature was 33°C or more, the sensor captured this moment as an event. After the 4-week CS treatment, the sensor was explanted and the patients were informed retrospectively about the sensor. The participants signed a second consent form prior to the readout of the sensor. The readout was performed with software from the same sensor company (Orthotimer). The wearing time of the compressive stockings was evaluated in hours in total and in percentage of the declared wearing time. Each sensor was tested before the implantation and after the readout to rule out any hardware failure. The sensor end test report ensured the sensor's function.

Outcomes

The outcome parameters were set preliminarily. Preoperatively and at the regular 6- and 12-week follow-up

Table 1. Demographics of the Intervention vs the Control Group.

Characteristic	Intervention Group (Compressive stockings) (n = 37)	Control Group (n = 39)
Female/male, No.	18/19	23/16
Age, mean (range), y	42 (18-70)	47 (19-79)
Weight, mean (range), kg.	79 (50-103)	80 (47-130)
Body mass index, mean (range), kg/m^2	27 (19-39)	28 (20-45)
Indication for surgery, No.		
Ankle arthritis	5	3
Ankle fracture	3	0
Ankle impingement	4	7
Ankle instability	3	2
Achilles tendon rupture	1	5
Disturbing metal	2	1
Flatfoot	3	2
Osteochondral lesion	7	10
Peroneal tendon rupture	9	9

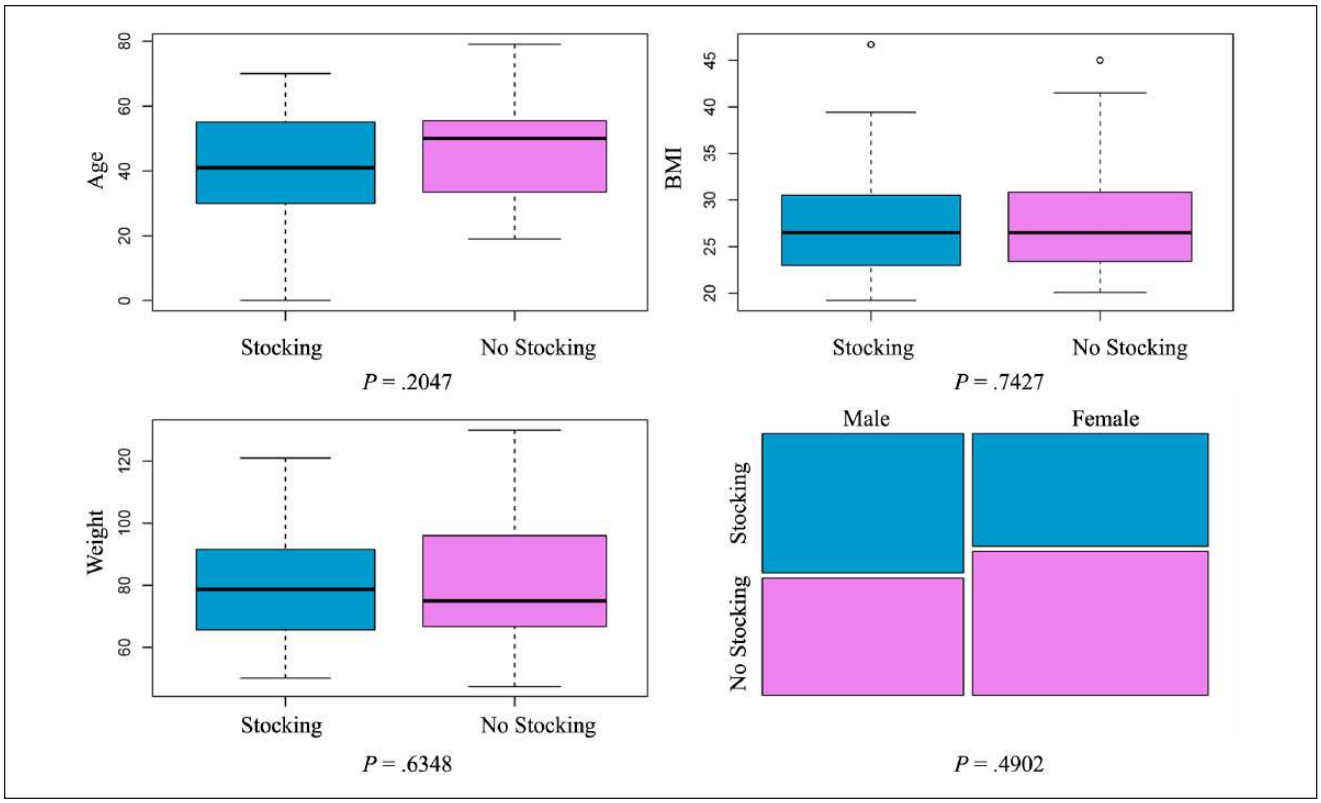

Figure 1. Boxplots showing no differences in patients' characteristics.

appointments, the same outcome parameters were obtained. Our primary objectives included ankle swelling, pain, quality of life, and functional scores. The swelling status was measured in millimeters at the intermalleolar ankle level. The pain status was evaluated by visual analog scale (VAS) from 0 (no pain) to 10 (most imaginable pain) points. The quality-of-life status was assessed using the Medical Outcomes Short Form Questionnaire (SF-36).[2] Functional outcomes were assessed using the American Orthopaedic Foot & Ankle Score (AOFAS).[6] Two authors (S.C. and R.S.) carried out the measurement of outcome parameters at different time points. Our secondary end point was the CS

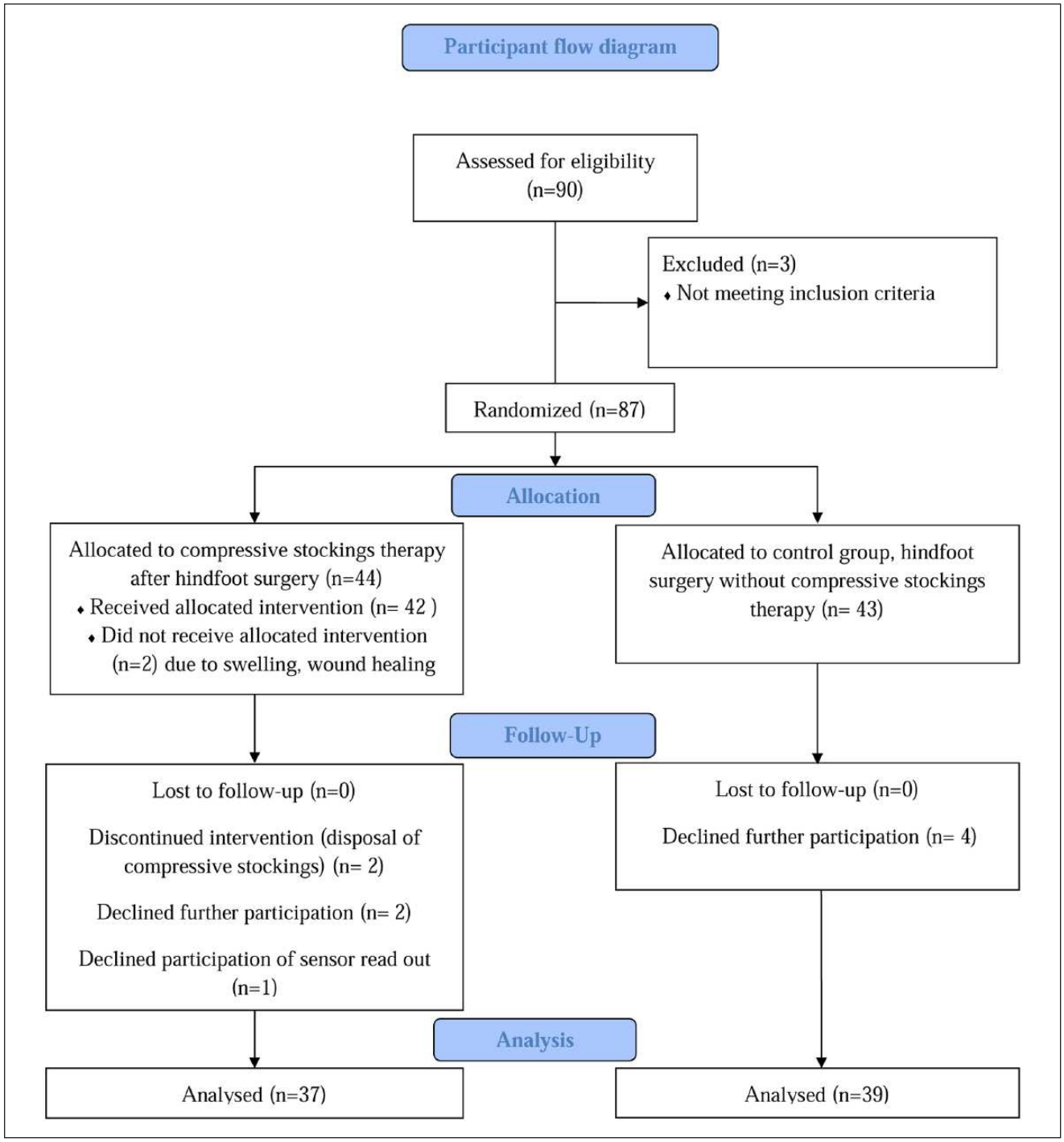

Figure 2. The flow diagram of study participants.

wearing time in absolute number (hours) and in relation to the declared wearing time (%).

Sample Size Calculation

The group size of the intervention group and the particular control group was defined after a power analysis that was performed by the Department of Biostatistics at Zurich University. Demanding the group power of 80% and a significance level of 5%, each of the 6 groups needed to have 37 participants to detect a difference of 10 mm in the ankle diameter. As only the hindfoot group was included, the aspired total number of participants was 74. The prospective recruitment stopped after the aspired number

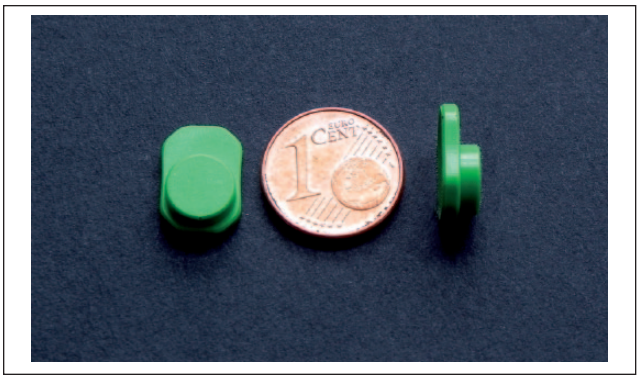

Figure 3. Green temperature capturing sensor in correlation to a one cent (€) coin.

of 74 participants with at least 37 patients in each arm was reached.

Randomization

Data collection was consistent with Good Clinical Practices guidance. Each patient participating in this study was assigned a unique identifier (ie, a study subject identification number) and data collected were confidentially recorded. All study numbers were allocated either to group I or group II. The randomized allocation of the study participant's numbers was performed before the recruitment phase started. Recruitment was performed by the REDCap software system (Vanderbilt University Medical Center).

Statistical Analysis

The study participants' demographics were analyzed using an analysis of variance according to their age, sex, body weight, and indications for surgery. Study data were collected and managed using the REDCap electronic data capture tool[3] (version 6.7.4 © 2015 Vanderbilt University). The nonpaired Student *t* test was used to compare the differences between the 2 groups. The differences within the same group before and after the index surgery were evaluated by using the paired Student *t* test. *P* values less than .05 were considered significant.

Results

All participants showed an increase of the ankle diameter from a mean of 226 (range, 173-280) mm preoperatively to a mean of 233 (range, 180-330) mm 6 weeks postoperatively and to a mean of 233 (range, 170-310) mm 12 weeks postoperatively. Group I had a mean diameter of 224 (range, 185-270) mm preoperatively, 235 (range, 190-330) mm 6 weeks postoperatively, and 234 (range, 190-285) mm 12 weeks postoperatively. The control group showed a mean ankle diameter of 228 (range, 173-280) mm preoperatively, 231 (range, 180-290) mm 6 weeks postoperatively, and 232 (range, 190-310) mm 12 weeks postoperatively. The mean pain level rose in all participants with statistical significance from 1.2 (range, 0-5) preoperatively to 1.7 (range, 0-7) 12 weeks postoperatively. Group I showed an increase of pain from 1 (range, 0-5) to 1.7 (range, 0-7) VAS points, and group II showed an increase of pain from 1.4 (range, 0-5) to 1.9 (range, 0-7) VAS points. The SF-36 score declined from a mean 37 (range, 5-61) points preoperatively to 34 (range, 10-61) points 12 weeks postoperatively ($P = .20$). Group I had 38 (range, 15-61) points preoperatively and 38 (range, 14-59) points 12 weeks postoperatively with no decline in quality of life, whereas the control group had a mean regression from 35 (range, 5-59) points to 30 (range, 10-69) points 12 weeks postoperatively. The AOFAS score improved in all patients from 71 (range, 12-95) preoperatively to 78 (range, 30-100) points 12 weeks postoperatively. The intervention group improved from 68 (range, 34-92) points preoperatively to 76 (range, 30-100) points 12 weeks postoperatively. The control group improved from 74 (range, 12-95) preoperatively to 76 (range, 45-100) points 12 weeks postoperatively.

The mean CS wearing time in the declared wearing period (4 weeks, 8 hours daily = 224 hours) was 136 (range, 0-470) hours, which corresponds to a mean wearing compliance rate of 65% (range, 0-209%). Sixteen participants of the intervention group wore the stockings on average 270 (range, 174-470) hours, which is 129% (range, 84-209%) of the declared wearing time. The remaining 21 participants wore the stockings an average of 34 (range, 0-148) hours, or 16% (range, 0-74%) of the declared wearing time. All results are summarized in Table 2.

The changes in the preoperative to the 12-week postoperative scores of all primary end points (swelling, pain, quality of life, and AOFAS) were not statistically different between the 2 groups (Figure 4). As the participants from group I showed different CS wearing behavior, a subgroup analysis was performed to compare the results between participants with high wearing (n = 16) vs those with low wearing compliance (n = 21). Patients with a wearing time of 80% or more were allocated to subgroup I (high-compliance group), and patients with less than 80% wearing time were in subgroup II (low-compliance group). Ankle swelling increased in subgroup I from a mean of 220 (range, 190-260) to 225 (range, 195-270) mm 6 weeks postoperatively and to a mean of 233 (range, 200-265) mm 12 weeks postoperatively. In subgroup II, the diameter increased from a mean of 227 (range, 185-270) mm preoperatively to a mean of 242 (range, 190-330) mm 6 weeks postoperatively and to a mean of 233 (range, 190-285) mm 12 weeks postoperatively. The pain level rose in subgroup I from a mean of 0.7 (range, 0-2.5) points to a mean of 1.2 (range, 0-5) points and in subgroup II from 1.2 (range, 0-5) points to a mean of 2.2 (range, 0-6) points 12 weeks postoperatively. Quality of life improved from preoperative 41 (range, 18-61) to 42 (range, 17-59) points 12 weeks postoperatively in subgroup I, whereas

Table 2. Results of All Participants and Comparison of Intervention Group vs Control Group.

	All Patients (N = 74)			Group I (n = 37)[a]			Group II (Control Group) (n = 39)		
Characteristic	Preoperatively, Mean (Range)	12 Weeks Postoperatively, Mean (Range)	*P* Value	Preoperatively, Mean (Range)	12 Weeks Postoperatively, Mean (Range)	*P* Value	Preoperatively, Mean (Range)	12 Weeks Postoperatively, Mean (Range)	*P* Value
Ankle swelling, mm	226 (173-280)	233 (170-310)	.312	224 (185-270)	234 (190-285)	.337	228 (173-280)	232 (190-310)	.221
Pain, VAS (points)	1.2 (0-5)	1.7 (0-7)	.045	1 (0-5)	1.7 (0-7)	.662	1.4 (0-5)	1.9 (0-7)	.212
Quality of life, SF-36 (points)	37 (5-61)	34 (10-61)	.201	38 (15-61)	38 (14-59)	.805	35 (5-59)	30 (10-60)	.081
AOFAS (points)	71 (12-95)	78 (30-100)	.073	68 (34-92)	76 (30-100)	.132	74 (12-95)	76 (45-100)	.579

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Score; SF-36 = 36-item Short Form questionnaire; VAS, visual analog scale.
[a]Wearing time h (total compressive stockings wearing time measured in absolute hours during the declared period from postoperative weeks 2-6) = 136 (range, 0-470) hours. Wearing time % (compressive stockings wearing time in hours in relation to the declared wearing time of 8 hours per day) = 65% (range, 0-209%).

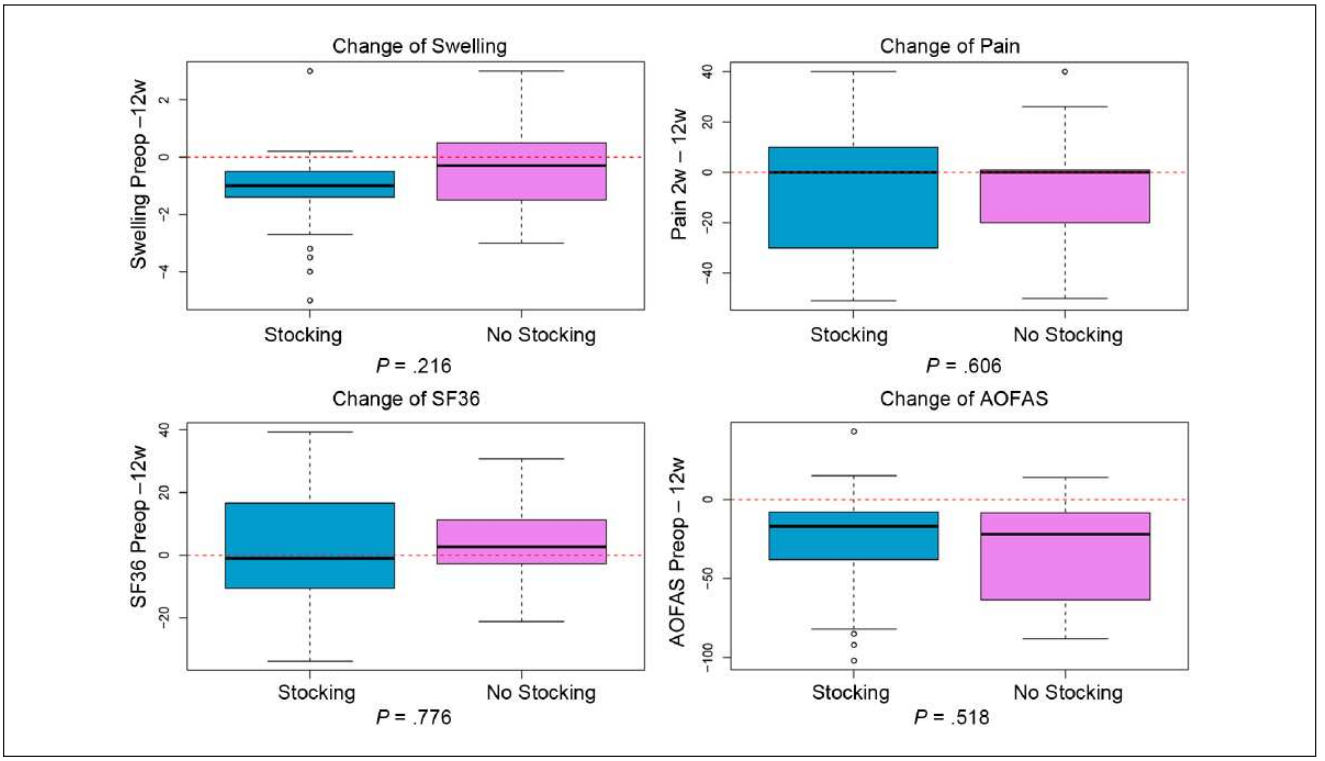

Figure 4. Boxplots showing the differences of the primary endpoint parameters between the intervention group (with compressive stockings) versus the control group (no compressive stockings).

in subgroup II, the mean score declined from 37 (range, 15-56) to 34 (range, 14-53) points. The AOFAS scores rose in subgroup I from 74 (range, 46-90) points preoperatively to 80 (range, 36-100) points 12 weeks postoperatively and in subgroup II from 66 (range, 34-92) points preoperatively to 73 (range, 30-100) points 12 weeks postoperatively. All changes between the preoperative and the 12-week postoperative scores (swelling, pain, SF-36, and AOFAS) were not statistically different between the 2 groups (Figure 5 and Table 3).

Complications

In 2 participants from the intervention group and 1 from the control group, wound-healing problems occurred 3 to 4 weeks after surgery. In all 3 patients, no further operative intervention was needed and the wound healed without any signs of an infection at the last follow-up visit.

Discussion

The study demonstrated that the postoperative use of CS showed no beneficial effects on patients' outcome parameters and was associated with a low wearing compliance. The change of the primary end points of patients who wore class II CS after hindfoot and ankle surgery shows no statistical difference in comparison to the control group, who wore no CS after the surgery. From other studies, it is known that patients' statements on wearing behavior of orthopedic devices are not reliable,[1,7,9,14]

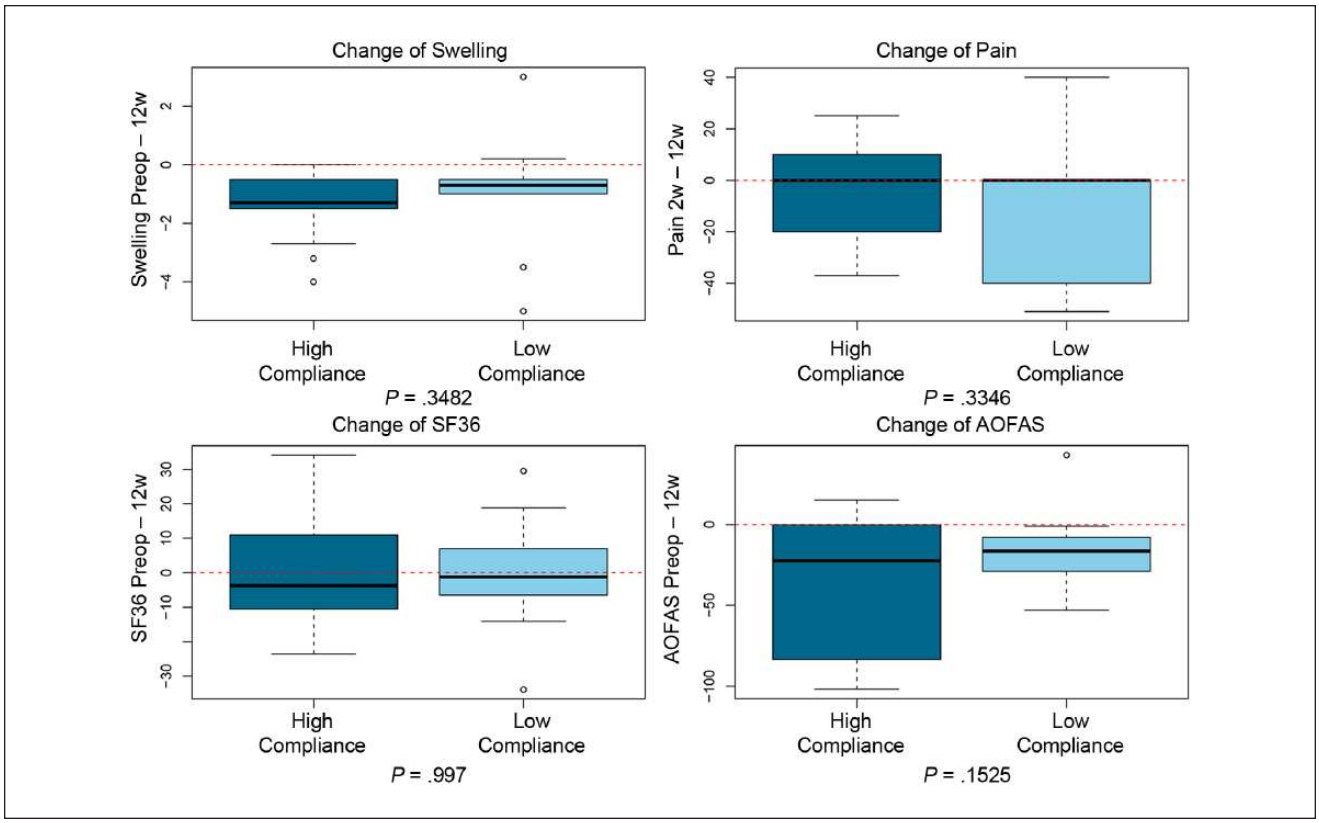

Figure 5. Boxplots showing the differences of the primary endpoints between patients from group I with high compliance vs patients from group II with low compliance.

Table 3. Results of Participants With High vs Low Wearing Compliance.

	Participants With High Wearing Compliance (>80%) (n = 16)			Participants With Low Wearing Compliance (<80%) (n = 21)		
Characteristic	Preoperatively, Mean (Range)	12 Weeks Postoperatively, Mean (Range)	*P* Value	Preoperatively, Mean (Range)	12 Weeks Postoperatively, Mean (Range)	*P* Value
Ankle swelling, mm	220 (190-260)	6 weeks: 225 (195-270) 12 weeks: 233 (200-265)	.534 .348	227 (185-270)	6 weeks: 242 (190-330) 12 weeks: 233 (190-285)	.381 .357
Pain, VAS (points)	0.7 (0-2.5)	1.2 (0-5)	.325	1.2 (0-5)	2.2 (0-6)	.132
Quality of life SF-36 (points)	41 (18-61)	42 (17-59)	.869	37 (15-56)	34 (14-53)	.544
AOFAS (points)	74 (46-90)	80 (36-100)	.352	66 (34-92)	73 (30-100)	.321

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Score; SF-36 = 36-item Short Form questionnaire; VAS, visual analog scale.
[a]Wearing time h (total compressive stockings wearing time measured in absolute hours during the declared period from postoperative weeks 2-6) = 270 (range, 174-470) hours for high-compliance group and 270 (range, 174-470) hours for low-compliance group. Wearing time % (compressive stockings wearing time in hours in relation to the declared wearing time of 8 hours per day) = 129% (range, 84-209%) for high-compliance group and 16% (range, 0-74%) for low-compliance group.

and the real CS wearing time and also the clinical effect of postoperative CS are actually unknown. In those studies that reported a positive influence of postoperative CS, the CS wearing behavior was not controlled by a sensor.[13,15] Our study is the first that controlled the patients' CS wearing compliance with a sensor. By knowing the objective patients' CS wearing time, it is more reliable to detect if any outcome differences are associated with the postoperative CS therapy or not.

The average CS wearing time from the 37 patients of the intervention group was 136 hours, which correlates to a compliance rate of 65%. More than the half of them (57%, n = 21) had a compliance rate of only 16% or an average absolute wearing time of 34 hours. Only 43% (n = 16) of the patients wore the CS for at least 80% of the declared wearing time of 8 hours per day for 4 weeks (224). Surprisingly, the changes of scores of these 16 patients who wore the stockings properly showed no statistical differences to the results of the 21 patients with noncompliance or low compliance or the control group. Therefore, it seems that the study hypothesis of the believed positive influence of CS after hindfoot or ankle surgery was incorrect.

The reason for the low compliance might be the uncomfortable constricting effect of CS, which was especially reported from the first participants with forefoot and midfoot surgeries. These (total of 4) adverse events led to a change in the study plan, and only patients with hindfoot and ankle surgery were recruited for the further study. This observation leads to the possible assumption that the use of grade II CS seems to be contraindicated after forefoot or midfoot surgery.

Because of the expected constricting effect of the postoperative use of CS, each participant was instructed to wear the CS in the morning when swelling of the feet is less than during the day. In addition, all patients were instructed to use an adjustment aid, which was a 100% nylon band to help to easily adjust the CS on the operated foot. Most of the patients with low compliance claimed they felt discomfort while wearing and taking off the CS. One would expect higher wearing compliance rates in patients with postoperative cast treatment. Interestingly, the cast rate in the low-compliance group was 71% (15 of the 21) and 63% (10 of the 16 patients) in the high-compliance group. Therefore, the adjustment of a postoperative cast did not influence the compliance rate in our study.

The study had 3 limitations. First, the power analysis recommended 37 participants for each arm to detect statistical differences. As the subanalysis of the intervention arm revealed 16 patients with high compliance and 21 patients with low compliance, it is possible that a statistical type II error existed due to the lack of power of this subanalysis. Therefore, the statement about the CS effect in patients with high wearing compliance has to be taken in that context, and maybe significant differences would be visible if the participant numbers of the subgroup analysis were high enough (≥37). Second, the fact that the patients had various operative procedures on their hindfoot might cause a problem of reproducibility of the therapy effect. By the use of a control group with the same distribution of operative interventions, the error should have been reduced. Finally, the follow-up period of 12 weeks was relatively short. However, as the results were already similar after 12 weeks, it is highly possible that no further differences would be seen in the future.

Conclusion

This study did not show any significant beneficial effects of postoperative CS therapy on subjective or objective outcome parameters of patients after hindfoot and ankle surgery. Its use after hindfoot surgery was associated with low patient compliance. Furthermore, the results of the 16 patients who wore the stockings with a high compliance rate were surprisingly not statistically different compared to the results of 21 patients with noncompliance or low compliance.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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